

### **REMARKS**

Claims 1-42 and 44-48 are pending in the present application. Applicants appreciate the Examiner's allowance of claims 1-24 and 45-48, and indication that claims 26, 38, 32-37, 39, 41, and 43 would be allowable if rewritten in independent form with the base and any intervening claims. Claims 25, 27, 29-31, 38, 40, 42, and 44 stand rejected. Based upon the foregoing amendments and following comments, Applicants respectfully request reconsideration and allowance of all pending claims.

In the specification, the cross-reference to related applications is amended to remove any ambiguity regarding the priorities being claimed in the present application. Entry of this amendment is respectfully requested.

Before addressing the specific rejections raised in the Office action, Applicants note that claims 13 and 24 are amended herein to correct typographical errors. Consideration and entry of these amendments are respectfully requested.

Turning to the Office action, claims 25, 27, 29-31, 38, 40, 42, and 44 stand rejected as allegedly anticipated by Cates et al. (U.S. Patent No. 6,056,768). Applicants respectfully traverse this rejection.

More specifically, independent claim 25, as well as claims 26-37 dependent directly or indirectly thereon, recites a method of positioning a pledget adjacent to the exterior surface of a blood vessel puncture site in a patient. The claimed method includes the steps of advancing a control head of a control tip through the puncture site and at least partially into the blood vessel and advancing an assembly over the control tip proximal portion and adjacent to an exterior surface of the blood vessel. The method further includes proximally retracting the control head, after the assembly advancing step, so that the control head is adjacent the pledget. In addition, the pledget is expelled from the delivery cannula. It is not seen that the prior art discloses or suggests such a method.

Cates et al. fail to disclose or suggest pledget positioning method in which a control head is proximally retracted, after an assembly advancing step, so that the control head is adjacent the pledget, as recited in claims 25-37. Instead, Cates et al. disclose a blood vessel sealing system

employing a temporary sealing assembly 11, a collagen plug 12, and an applicator 14. The temporary sealing assembly 11 includes an expandable tamponading member 21 mounted on a flexible control member 20. The temporary sealing assembly 11 is threaded through a guide sheath GS so that the tamponading member 21 is located inside a blood vessel lumen BVL. The tamponading member 21 is then expanded, such as by air inflation. As noted at Column 9, lines 16-44 of Cates et al., the physician must then physically pull back on the control member 20 so that the tamponading member 21 is pulled back up against the inside end of the blood vessel puncture BVP. After the tamponading member 21 is so positioned, the applicator 14 with collagen plug 12 is inserted over the control member 20 and advanced there along until a barrel 50 of the applicator is located near the outside end of the blood vessel puncture BVP. Consequently, if the tamponading member 21 is considered to be the claimed control head and the applicator 14 is considered to be the claimed assembly, then it is evident that the tamponading member is not proximally retracted, after the applicator is advanced, so that the tamponading member is adjacent the applicator, as specified in claims 25-27.

Because Cates et al. does not disclose each of the elements recited by claims 25-37, it follows that these claims are not anticipated thereby. In addition, Cates et al. fail to disclose or suggest that it would be desirable or even possible to provide a pledget positioning method in which a control head is proximally retracted, after an assembly advancing step, so that the control head is adjacent a pledget, and hence a prima facie case of obviousness has not been established.

With regard to claims 38-43, independent claim 38 has been amended to incorporate the subject matter of claim 43, which was indicated as reciting allowable subject matter, and claim 43 has been canceled. Accordingly, claims 38-42 are now in condition for allowance.

Finally, claim 44 is amended herein to more clearly define over the cited prior art. Amended claim 44 now specifies a method of at least partially controlling blood flow through a puncture site in a blood vessel wall including the steps of inserting a control tip having a control head with a proximal end portion through the vessel wall at the puncture site and so that the control head proximal end portion is inserted at least partially into the blood vessel and positioning a pledget adjacent to an outer surface of the blood vessel wall at the puncture site

with the control tip still at least part in the vessel puncture site, the pledget including a distal end portion. The method further includes the step of repositioning the control tip with respect to the pledget distal end portion thereby to control blood flow therebetween. It is not seen that the prior art discloses or suggests such a method.

Cates et al. fail to disclose or suggest a method of at least partially controlling blood flow through a puncture site in a blood vessel wall including the step of repositioning a control tip with respect to a pledget distal end portion to control blood flow therebetween, as recited in claim 44. Instead, as noted above with respect to claims 25-37, Cates et al. disclose controlling blood flow solely with the tamponading member 21. Consequently, if the tamponading member 21 is considered to be the claimed control tip, then it is evident that the tamponading member is not repositioned with respect to the applicator to control fluid flow, as specified in claim 44.

Because Cates et al. does not disclose each of the elements recited by claim 44, it follows that these claims are not anticipated thereby. In addition, Cates et al. fail to disclose or suggest that it would be desirable or even possible to provide a method of at least partially controlling blood flow through a puncture site in a blood vessel wall including the step of repositioning a control tip with respect to a pledget distal end portion to control blood flow therebetween, and hence a prima facie case of obviousness has not been established.

**CONCLUSION**

It is submitted that the present application is in good and proper form for allowance. A favorable action on the part of the Examiner is respectfully solicited.

If, in the opinion of the Examiner a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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